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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,323	12/10/2001	Derek J. Hei	282172000404	7855

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EXAMINER	
NAFF, DAVID M	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/016,323	HEI ET AL.	
	Examiner	Art Unit	
	David M. Naff	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *58-97 and 104* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *58-97 and 104* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/30/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/30/04 has been entered.

An amendment filed 4/30/04 canceled claims 98-103 and amended claim 104.

Claims examined on the merits are 58-97 and 104 which are all claims in the application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

Claims 58-73, 75-78, 81-85, 87-97 and 104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hei (WO 96/40857) or Hei (6,544,727 B1) or Foley et al (6,319,662) or Lee (6,228,995) in view of Groeger et al (5,605,746) and Samejima (4,160,059).

The claims are drawn to a pathogen-inactivating compound adsorption system for reducing the concentration of a low molecular weight pathogen-inactivating compound in a biological composition. The system contains a housing compatible with the biological composition containing porous adsorbent resin particles having a

particle diameter of about 1 μm to about 200 μm immobilized by a matrix. The particles have an affinity for the pathogen-inactivating compound and the system is configured to remove the pathogen-inactivating compound from the biological composition in a flow process, and so that the biological composition treated with the system maintains sufficient biological activity to be suitable for infusion within a human. Also claimed are method of using the system to treat a biological composition.

Hei (WO) discloses a method and device for removing psoralens and psoralen photoproducts from blood products using a resin capable of adsorbing the psoralens. The resin can be in a housing (page 75) and have a particle size (page 82) as claimed.

Hei ('727) disclose the same type of method and device as Hei (WO).

Foley et al disclose adding a viral inactivating agent such as a psoralen compound for virus inactivation in a body fluid such as a blood product, and then removing the agent from the blood product with an adsorptive material (col 4, line 42 to col 5, line 61). The adsorptive material may be beads having a particle size of 30-2000 μm, an average pore diameter of 45-300 angstroms, and a surface area of 150-1600 sq. meters/gram dry bead (col 5, lines 18-20). The beads are enclosed in a container, cartridge or other means for housing the beads (col 2, lines 30-33, and col 4, lines 43-47) through which the blood product passes.

Lee discloses using adsorbent beads to remove viral inactivating agents such as psoralens and psoralen degradation products from a blood product by passing the blood product through a cartilage containing the beads (col 2, lines 23-37, and Figures 2 and 3). The beads can have a diameter of 0.1 to 2 mm (100-2000 μm) (col 2, line 31).

Groeger et al disclose (col 3, lines 11-22) a fibrous structure containing a composite fiber matrix loaded with adsorbent functional particles such as activated carbon beads (col 5, line 50). The particles may have a size of 1 micron to 3-5 mm depending on the web structure (col 6, lines 12-30). A preferred size for activated carbon particles is about 400 to 500 microns (col 6, line 19). The fibrous structure has applications such as preparing high purity water, and for color or byproduct removal from whiskey and vinegar (col 10, lines 25-27).

Samejima discloses a fiber matrix loaded with an adsorptive material such as activated carbon (col 1, lines 11-39). Activated carbon has a surface area of 800-1800 m^2/gm (col 1, line 29). The adsorptive material may have various uses including purification of tap water (col 1, lines 35-36).

It would have been obvious to provide the adsorbent beads of Hei (WO) or ('727) or Foley et al or Lee within a matrix as taught by Groeger et al and Samejima to obtain an expected advantage of the matrix holding the beads to prevent bead migration and bead abrasion,

to provide three dimensional distribution and spacing of the beads, to facilitate handling of the beads and separation of the beads from a blood product, and to obtain the function of the matrix as an adsorbent in addition to the beads or as a filter. Hei discloses a housing for the beads, and the container or cartridge of Foley et al or Lee, which contains the beads, provides a housing for the beads. The adsorbent beads in the housing, container or cartridge of Hei or Foley et al or Lee is used to treat a blood product to produce a blood product for infusing into a patient (Foley et al (col 3, lines 5-15) and Lee (col 3, lines 35-36). When using a matrix such as a fibrous matrix to hold the beads, it would have been obvious to use a matrix that results in a blood product suitable for infusion into a human since this is an objective of Hei, Foley et al and Lee. Furthermore, the particle-containing matrix of Groeger et al or Samejima can be used for purifying water or liquids to be consumed by a human, and such a matrix would appear to be capable of providing a blood product suitable for infusing into a human. The conditions of dependent claims would have been matters of obvious choice within the skill of the art in view of the disclosures of the references and knowledge common in the art.

Response to Arguments

It is granted as urged by applicants that Groeger et al and Samejima may be adsorbing materials from products other than blood products such as ingestible products including whisky, cider and water. However, the advantages of having particles in a matrix would

have been expected to be obtained when adsorbing viral inactivating agents in blood as disclosed by Hei or Foley et al or Lee. When desiring to adsorb materials from blood, it would have been obvious to look to the use of adsorbents from removing materials from other liquids. Adsorbing materials from liquids other than blood such as ingestible liquids is not outside the endeavor of the present invention and is not nonanalogous art. Additionally, the system presently claimed can be used for adsorbing materials from products disclosed by Groeger et al and Samejima.

A matrix holding the beads to prevent bead migration and bead abrasion, to provide three dimensional distribution and spacing of the beads, to facilitate handling of the beads and separation of the beads as suggested by Groeger et al and Samejima would have been motivation to put the beads of the primary references in a matrix as disclosed by Groeger et al and Samejima.

It is granted as urged by applicants that Groeger et al and Samejima, as well as Foley et al and Lee, may use a particle size outside the claimed particle size range. However, these references may also use particles inside the claimed range, and it would have been obvious to use any of the particles sizes disclosed by the references. While Samejima does not disclose a particle size, the activated carbon used by Samejima is particulate and would have a size within the claimed range.

Applicants point to claim 59 as requiring a sintered polymeric matrix not being disclosed in the references. However, Groeger et al

disclose using thermal bonding by using thermoplastic polymers to bond fibers together and to bond fibers to the particles (col 3, lines 32-37 and col 11, lines 11-16). This melt bonding would be sintering as disclosed in the present specification. Also, Samejima uses heat-fusible fibers (col 4, line 25), and the use of heat-fusible fibers is to bond the fibers together by partial melting of the fibers. The present claims do not exclude a fibrous matrix prepared by thermal bonding as suggested by the secondary references, and claim 59 does not exclude the matrix being formed from sintered fibers.

Claim Rejections - 35 USC § 103

Claim 74 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 58-73, 75-78, 81-85, 87-97 and 104 above, and further in view of Davankov et al (5,773,384).

The claim requires the adsorbent resin particles to be hypercrosslinked.

Davankov et al disclose the use of hypercrosslinked polystyrene particles as an advantageous adsorbent to remove toxicants from blood.

It would have been obvious to use the hypercrosslinked polystyrene particles of Davankov et al for their expected advantage as the adsorbent beads of Hei or Foley et al or Lee when the beads are in a matrix as suggested by Groeger et al and Samejima.

Claim Rejections - 35 USC § 103

Claims 79 and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 58-73, 75-78,

81-85, 87-97 and 104 above, and further in view of Horowitz et al (6,294,361).

The claims require the resin particles to have affinity for a nucleic acid-binding compound having an electrophilic group that reacts with a nucleophilic group of a quencher.

Horowitz et al discloses (col 7, line 57 to col 8, line 16) the use of a quencher when inactivating a virus in blood with a psoralen compound.

When providing the beads of Hei or Foley et al or Lee in a matrix for removing a viral-inactivating agent such as a psoralen compound from a blood product as set forth above, it would have been obvious use a quencher for its expected function as taught by Horowitz et al, and the reacting of an electrophilic group of the psoralen compound with a nucleophilic group of the quencher would have been inherent.

Claim Rejections - 35 USC § 103

Claim 86 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 58-73, 75-78, 81-85, 87-97 and 104 above, and further in view of Wollowitz et al (5,593,823).

The claim requires specific psoralen compounds as the pathogen-inactivating compound.

Wollowitz et al disclose psoralen compounds that have improved pathogen-inactivating activity in blood that can be the same as presently claimed. For example, see the paragraph bridging cols 4 and 5, and col 65, lines 35-51.

When providing the beads of Hei or Foley et al or Lee in a matrix for removing a viral-inactivating agent from a blood product as set forth above, it would have been obvious to use the psoralen compounds of Wollowitz et al as the psoralen compound to obtain their improved pathogen inactivating activity.

Response to Arguments

In response to the rejections of claims 74, 79, 80 and 86 above, applicants assert that these claims are dependent on claim 58, and are patentable for the same reasons presented in regard to claim 58. However, for reasons set forth above, claim 58 is still considered obvious.

Claim Rejections - 35 USC § 103

Claims 58-97 and 104 are provisionally rejected under 35 U.S.C. 103(a) as being obvious over copending Application No. 10/051,976 or 09/872,384 in view of Groeger et al and Samejima, which application No. 10/051,976 or 09/872,384 has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e) if published or patented. This provisional rejection under 35 U.S.C. 103(a) is based upon a presumption of future publication or patenting of the conflicting application.

The invention, Groeger et al and Samejima are described above.

Copending application 10/051,976 discloses the same as Hei (WO) and 09/872,384 discloses the same as Hei ('727).

For reasons set forth above, it would have been obvious to provide the adsorbent beads of the copending applications within a matrix as taught by Groeger et al and Samejima to obtain an expected advantage of the matrix holding the beads to prevent bead migration and bead abrasion, to provide three dimensional distribution and spacing of the beads, to facilitate handling of the beads and separation of the beads from a blood product, and to obtain the function of the matrix as an adsorbent in addition to the beads or as a filter. The conditions of dependent claims are disclosed by the copending applications, or would have been obvious from conditions disclosed by the copending applications and Groeger et al and Samejima.

This provisional rejection might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by a showing of a date of invention for the instant application prior to the effective U.S. filing date of the copending application under 37 CFR 1.131. For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Double Patenting

Claims 58-97 and 104 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 53-110 of copending Application No. 09/972,323 in view of Foley et al or Lee or Hei (WO) or ('727).

The claimed invention, Foley et al, Lee and Hei are described above.

The claims of the copending application are drawn to a method of reducing the concentration of a low molecular weight compound in an aqueous biological composition by contacting the composition batchwise with an adsorption medium comprising porous absorbent particles immobilized by a matrix wherein the particles have a diameter ranging from about 100μm to about 1500 μm to adsorb the low molecular weight compound.

It would have been obvious to enclose the matrix and adsorbent particles of the device of the copending application claims in a flow through housing as suggested by Foley et al or Lee or Hei using adsorbent beads in a flow through housing to obtain continuous flow when removing a viral inactivating agent from a blood product.

This is a provisional obviousness-type double patenting rejection.

Double Patenting

Claims 58-97 and 104 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as

being unpatentable over claims 53-115 of copending Application No. 10/011,202 in view of Foley et al or Lee or Hei (WO) or ('727).

The claimed invention, Foley et al, Lee and Hei are described above.

The claims of the copending application are drawn to a pathogen-inactivating compound adsorption system for reducing the concentration of a low molecular weight pathogen-inactivating compound in a biological composition containing cellular elements. The system contains a housing compatible with the biological composition containing porous adsorbent particles having a particle diameter of about 100 μm to about 1500 μm immobilized by a matrix. The particles have an affinity for the pathogen-inactivating compound and the system is configured to remove the pathogen-inactivating compound from the biological composition in a batch process, and so that the cellular elements of the biological composition treated with the system maintain sufficient biological activity so that the biological composition is suitable for infusion within a human. Also claimed is a method of using the system to treat a biological composition.

It would have been obvious to provide the matrix and adsorbent particles in the housing of the system of the copending application claims for flow through the housing instead of for a batch process as suggested by Foley et al or Lee or Hei using adsorbent beads in a flow through housing to obtain continuous flow when removing a viral inactivating agent from a blood product.

This is a provisional obviousness-type double patenting rejection.

Response to Arguments

Applicants indicate they are willing to file a terminal disclaimer in a later allowed application.

Double Patenting

Claims 58-97 and 104 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 and 27-54 of copending Application No. 10/051,976 or claims 1-24 of copending Application No. 09/872,384 in view of Groeger et al and Samejima, and if necessary in further view of Hei (WO) or ('727).

The claims of the copending applications require removing psoralen from blood using a particulate resin.

Groeger et al, Samejima, and Hei (WO) and ('727) are described above.

For reasons set forth above when applying Groeger et al and Samejima, it would have been obvious to provide the resin particles of the claims of the copending applications in a matrix as suggested by Groeger et al and Samejima. If needed, Hei (WO) or ('727) would have suggested a housing for the particles, and conditions of dependent claims not disclosed by the claims of the copending applications.

This is a provisional obviousness-type double patenting rejection.

Double Patenting

Claims 58-97 and 104 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-47 of U.S. Patent No. 6,544,727 B1 in view of Groeger et al and Samejima, and if necessary in further view of Hei (WO).

The claims or the patent require removing psoralen photoproducts for blood with a particulate resin which can be in a housing.

For reasons set forth above when applying Groeger et al and Samejima, it would have been obvious to provide the resin particles of the claims of the patent in a matrix as suggested by Groeger et al and Samejima. If needed, Hei (WO) would have suggested the claimed particles size, and conditions of dependent claims not disclosed by the claims of the patent.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David M. Naff
Primary Examiner
Art Unit 1651

DMN
5/28/04